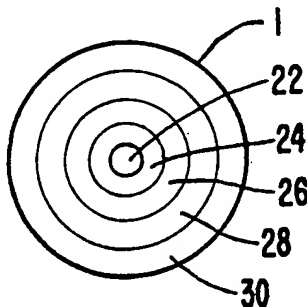


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61F 2/14, 2/16	A1	(11) International Publication Number: WO 89/ 02251 (43) International Publication Date: 23 March 1989 (23.03.89)
(21) International Application Number: PCT/US88/03020 (22) International Filing Date: 9 September 1988 (09.09.88) (31) Priority Application Number: 095,360 (32) Priority Date: 10 September 1987 (10.09.87) (33) Priority Country: US (71)(72) Applicant and Inventor: NIELSEN, James, McHenry [US/US]; Sunset Coachman Center, Suite 300, 2339 Sunset Point Road, Clearwater, FL 33575 (US). (74) Agents: STONE, Samuel, B. et al.; Lyon & Lyon, 611 West Sixth Street, 34th Floor, Los Angeles, CA 90017 (US).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: MULTIFOCAL INTRAOCULAR LENS**BEST AVAILABLE COPY****(57) Abstract**

Multifocal lenses (1) are formed having a substantially circular central region (22) having a first optical power, surrounded by a plurality of concentric ring regions (24, 26, 28, 30) which alternate between at least two optical powers, one of which may be the first optical power. Preferably, the central region (22) is powered for near vision. For example, one embodiment of the invention is a bifocal lens (1) having a central near-vision portion (22), a first concentric ring region (24) powered for distance vision, and a second concentric ring region (26) having the same power as the central region (22).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

DESCRIPTIONMultifocal Intraocular LensBackground of the Invention

5 The present invention relates to multifocal intraocular lens for implantation in the human eye having a plurality of concentrically-arranged regions alternately powered for differing vision ranges, e.g., near and far vision, surrounding a substantially circular central region.

10 Various lenses have been disclosed which have circular central region surrounded by a single ring. For example, U.S. Patent No. 3,420,006 discloses bifocal contact lenses in which a central region powered for distance vision is surrounded by a ring powered for near vision, while U.S. Patent No. 3,270,007 discloses the reverse configuration. U.S. Patents Nos. 3,726,587 and 4,636,049 also disclose bifocal contact lenses in which a central region powered for near vision is surrounded by a ring powered for far vision. These latter lenses are said
20 to work better than earlier lenses having the near-vision portion outside the distance portion.

U.S. Patent No. 4,573,775 discloses soft multifocal contact lenses having a vertical array decreasing power. U.S. Patent No. 4,580,882 discloses a contact lens
25 in which the power varies continuously outward from a central area for distance vision.

U.S. Patent No. 4,636,211 discloses bifocal intraocular lenses having a central region powered for near vision and a single surrounding ring powered for
30 distance vision.

Each of these earlier disclosures offers some optical theory as to the reason for operation of a particular lens design, and U.S. Patent Nos. 3,726,387, 4,636,049 and 4,636,211 specify particular preferred sizes

for the near and far vision portions. Such size specifications represent a compromise, however, in order to provide adequate light collecting area in both the far and near vision segments if significant pupillary excursion
5 occurs under different lighting conditions. This compromise is necessary if the known lenses are to provide both distance and near vision at both extremes of high and low lighting levels and thus small and large pupillary aperture, but leads to decreased efficiency of near vision
10 at low lighting levels (assuming a near-vision central portion) and decreased efficiency for far vision at high light levels. The claimed invention overcomes this difficulty, thus providing bifocal intraocular lenses which more closely approximate the vision range of a
15 natural lens.

Summary of the Invention

According to the invention, multifocal lenses are formed having a substantially circular central region having a first optical power, surrounded by a plurality of
20 concentric ring regions which alternate between at least two optical powers, one of which may be the first optical power. Thus, the concentric ring regions begin with an innermost ring region having a power different from the power of the ring region, with the proviso either that at
25 least one of the ring regions has the same power as the central region, or that at least two of the ring regions have the same power. Preferably, the central region is powered for near vision. For example, one embodiment of the invention is a bifocal lens having a central near-
30 vision portion, a first concentric ring region powered for distance vision, and a second concentric ring region having the same power as the central region.

Brief Description of the Drawing

Figure 1 shows a sectional view of a human eye with the intraocular multifocal lens implanted in the anterior chamber.

5 Figure 2 shows a sectional view of a human eye with the intraocular lens implanted in the posterior chamber.

 Figure 3 shows a sectional view of a human eye with an intraocular multifocal lens permanently fixed on
10 the cornea beneath the epithelium.

 Figure 4 shows a sectional view of a human eye with an intraocular multifocal lens permanently fixed in the cornea in the stroma layer.

 Figure 5 shows a sectional view of a human eye
15 with an intraocular multifocal lens permanently fixed in a pocket in the cornea between the epithelium and endothelium.

 Figure 6 shows a sectional view of a human eye with an intraocular multifocal lens permanently fixed
20 inside the cornea.

 Figure 7 is a plan view of an intraocular bifocal lens according to the invention.

 Figure 8 shows a sectional view of the intraocular lens having a plano-convex shape.

25 Figure 9 is a sectional view of the intraocular multifocal lens having a bi-convex shape.

 Figure 10 shows a convex-plano-convex lens.

 Figure 11 shows a convex-concave intraocular lens.

30 Detailed Description of the Invention

Intraocular lenses are surgically implanted lenses used as a replacement for, or in some cases as an adjunct to the natural lens. For example, after a cataract or clear lens extraction operation in which the
35 natural lens is removed, an intraocular lens may be implanted in either the anterior chamber or the posterior

chamber 12 of the human eye 10 as shown in Figures 1 and 2 respectively. In either case, the lens may be affixed in place using any of a wide variety of haptic designs which are well known in the art.

5 Intraocular lenses may also be implanted by corneal-inlay techniques, i.e., they may be surgically placed in various positions in or on the cornea 7. Figures 3-6 exemplify these various positions within the cornea; i.e., just below the epithelial layer (Fig. 3),
10 within the stroma layer (Fig. 4), within the cornea in a surgically created pocket (Fig. 5), and against the inner corneal surface (Fig. 6). The intraocular lens according to the invention may advantageously be utilized in any of these environments.

15 Figure 7 shows one embodiment of a bifocal intraocular lens according to the invention. This lens 1 has a substantially circular central region 22, a first concentric ring region 24 coaxially surrounding the central region 22, and three more concentric ring regions
20 26, 28 and 30 coaxially surrounding the first concentric ring region 24. If the central region 22 is powered for near vision, then concentric ring regions 24 and 28 are powered for far vision, while concentric ring regions 26 and 30 are powered for near vision. In this way, an
25 alternating pattern of near-far-near-far-near is obtained in the central and ring regions of the lens. In other embodiments of the invention, fewer or more concentric ring regions might be used. In addition, rings having additional powers may be incorporated in an alternating
30 fashion to give a multifocal lens. In a multifocal lens, the concentric ring segments may be an alternating array of regions of two or more powers all of which are different from the power of the central circular region. Alternatively, the ring segments may include rings of the
35 same power as central circular region, along with ring segments of two additional powers. Thus, for example, in

a trifocal lens having lens powers designated A, B, and C, the concentric rings might be arrayed as B-C-B, B-C-B-C, B-C-A-B, or B-C-A-B-C around a central circular portion of power A.

5 The intraocular lens according to the invention advantageously may have a piano-convex shape (Figure 8) or a bi-convex shape (Figure 9). In addition, lenses according to the invention may have a convex-concave shape (figure 10) or a convex-plano-convex shape (Figure 11) or
10 a biconcave shape.

 Pseudophakic eyes generally exhibit less pupillary excursion than average, due to the general tendency for this type of surgery to be performed on elderly patients who exhibit varying degrees of senile miosis. In
15 addition, some degree of miotic behavior may be the result of the surgery itself. Nevertheless, some degree of pupillary excursion due to differing lighting conditions and the normal accommodation for close focusing occurs in many patients. The lenses according to the invention provide
20 superior vision of both near and far objects throughout the range of pupillary excursion. This is achieved by selecting the relative sizes of the regions such that as the pupillary aperture changes the portion of a bifocal lens exposed always has about one-half of the pupillary
25 area powered for near vision and the other half powered for far vision. In a multifocal lens having three or more powers, the relative areas are similarly balanced to achieve optimum light transmission for segments of each power under all conditions.

30 In practice, this can be achieved with a lens having an overall diameter of about 6 to 7 mm in which the central region is from 1 mm to 3 mm and the concentric ring regions have a radial thickness of about 0.125 mm or more. Given the normal diameter for the lens, the maximum
35 radial thickness of any one ring region is about 2 mm. The rings can differ in radial thickness, for example by becoming successively narrower so that the area of the

rings is constant, or the radial thickness of the rings can be kept constant. The eye size and extent of pupillary excursion in an individual patient should be considered in establishing the actual dimensions of a lens.

5 The lenses according to the invention provide multifocal vision by relying upon the nervous system's inherent ability to selectively perceive one of two or more sets of optical inputs, e.g., near and far objects. In order for adequate differentiation and rapid neuro-
10 transfer between the two sets of inputs to be achieved, a difference in effective power of at least 2.5 diopters is generally necessary although this will vary somewhat from patient to patient. Some patients may achieve effective neurotransfer with differences as low as 1 diopter, while
15 others may require differences as large as 3 diopters. In additional corneal inlay usage will require a lesser difference because of the increased distance from the retina.

 The actual powering of the far and near vision regions is selected based on the needs of the individual
20 patient, but the average patient will require a power of +10 to +30 diopters in the far vision regions of the lens, and a power of +10 to +40 diopters in the near vision region of the lens.

 The lenses according to the invention can be fabri-
25 cated by lathe cutting, compression or injection molding, photoetching, milling or electro-forming. The near optic may be placed on either surface of the lens with the power corrected accordingly. Similarly, the concentric ring regions may be formed by varying the curvature of con-
30 centric ring portions on either the inner or outer surface, or both. The lenses may also be fabricated using materials having different refractive indices for the near and far vision regions.

Claims

1. A multifocal lens adapted for intraocular implantation in a human eye comprising a transparent lens body having a substantially circular central region having a first optical power; and a plurality of concentric ring regions coaxially surrounding said central region, the innermost of said ring regions having a second optical power different from said first optical power, and each subsequent ring region having an optical power different from the optical power of the ring region immediately inward therefrom, with the proviso that said plurality of concentric ring regions include either at least one ring region having said first optical power, or at least one ring region having said first optical power, or at least two ring regions which have the same power.

2. A lens according to claim 1, wherein the central region is powered for near vision.

3. A lens according to claim 1. wherein the lens is a bifocal lens, and the subsequent ring regions are alternately of said first and second powers.

4. A lens according to claim 3, wherein the central region and ring regions are sized such that over an average range of a patients pupillary excursion about one-half of the exposed portion of the lens is powered for near vision.

5. A lens according to claim 1 wherein the central region is from about 1 to 3 mm in diameter.

6. A lens according to claim 5, wherein the concentric ring regions have a radial thickness of from about 0.125 mm to about 2 mm.

7. A lens according to claim 6, wherein the concentric ring regions all have equal area.

8. A lens according to claim 1, wherein the concentric ring regions all have equal thickness.

5 9. A lens according to claim 1, further comprising haptics for fixing the lens within the anterior or posterior chamber of the eye.

10 10. A bifocal lens according to claim 1, wherein the difference between the near and far vision powers is from about 1 to 3 diopters.

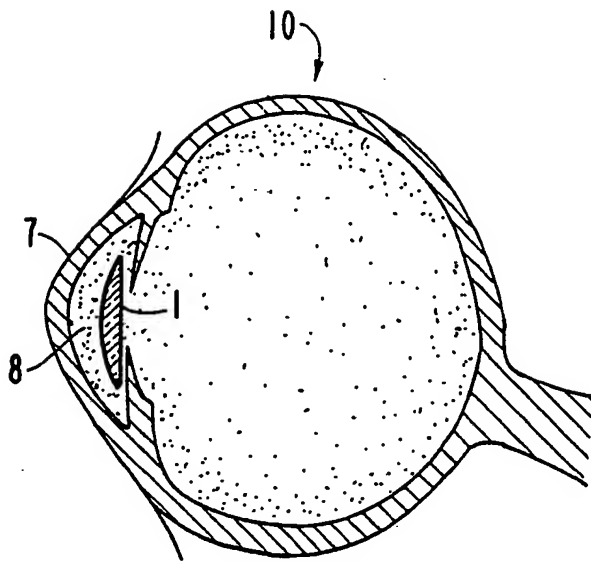


FIG. 1.

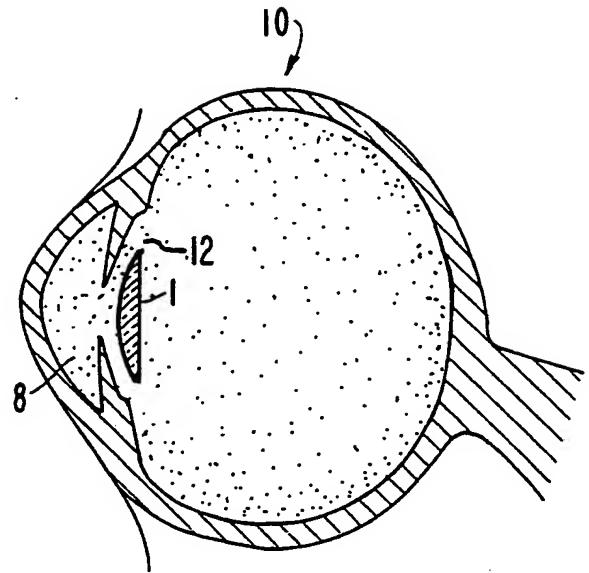


FIG. 2

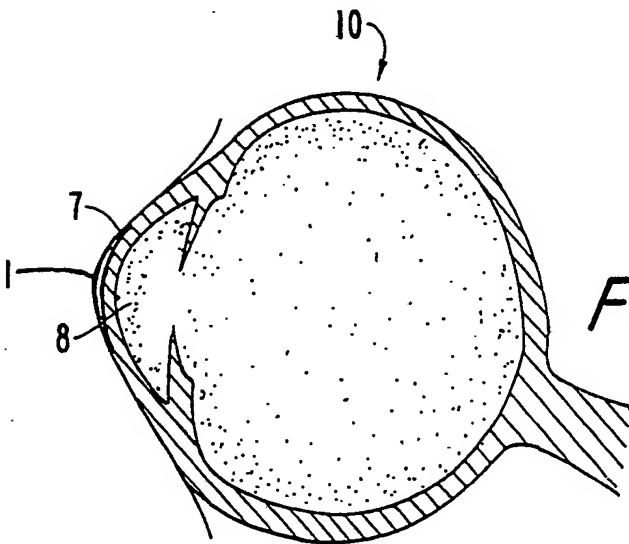


FIG. 3.

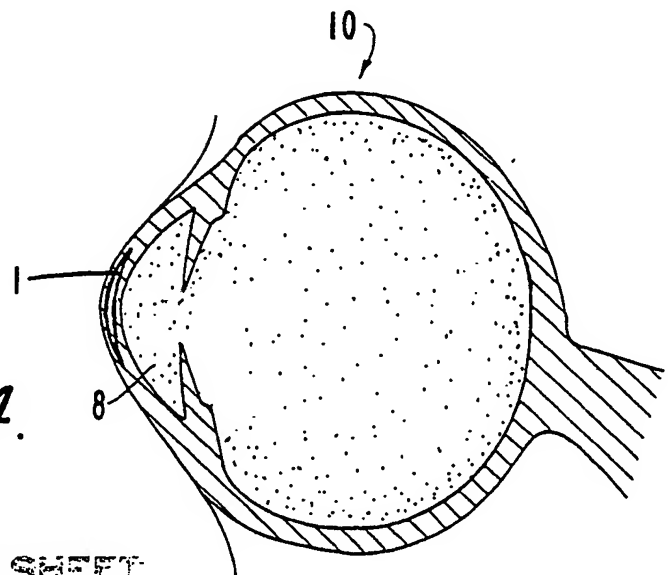


FIG. 4.

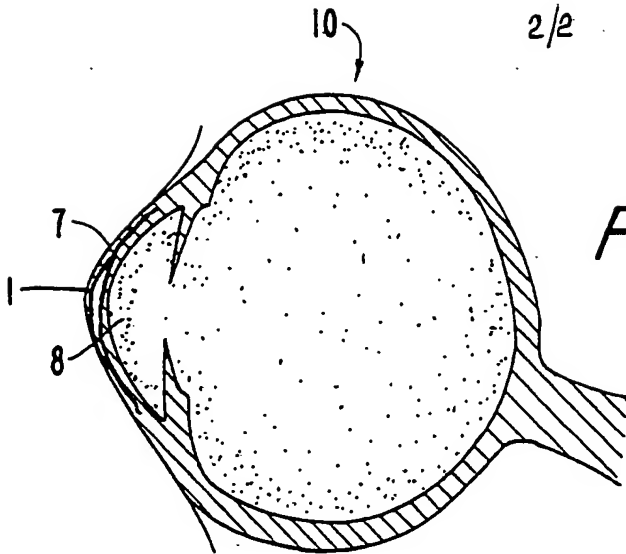


FIG. 5.

FIG. 6.

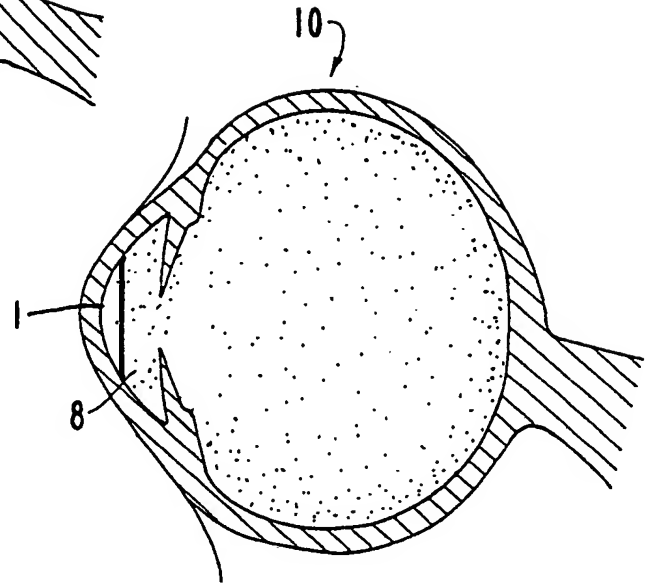


FIG. 7. ✓

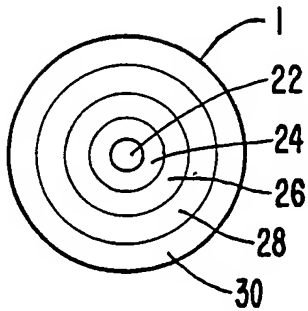


FIG. 8.



FIG. 9.



FIG. 10.

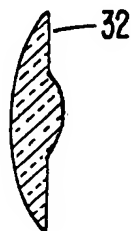
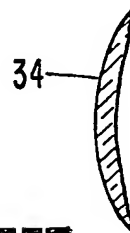


FIG. 11.



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 88/03020

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (4) : A61F 2/14, 2/16

U.S. CL : 623/5,6, 351/161,168

II. FIELDS SEARCHED

Minimum Documentation Searched ⁷

Classification System

Classification Symbols

U.S.

623/4, 5, 6, 351/161,168

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁸

III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹

Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	US,A, 4,636,211 (NIELSEN ET AL) 13 January 1987 (See column 2, lines 3-7)	10
Y	WO,A, WO 86/03961 (VANNAS) 17 July 1986 (See Figure 7, page 1, lines 18-25, page 2, lines 17-18, page 4, lines 27-31 and page 5, lines 1-2.	1-10

^{*} Special categories of cited documents: ¹⁰

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search
13 December 1988

Date of Mailing of this International Search Report

03 FEB 1989

International Searching Authority
ISA/USA

Signature of Authorized Officer

Ronald L. Frinks

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.